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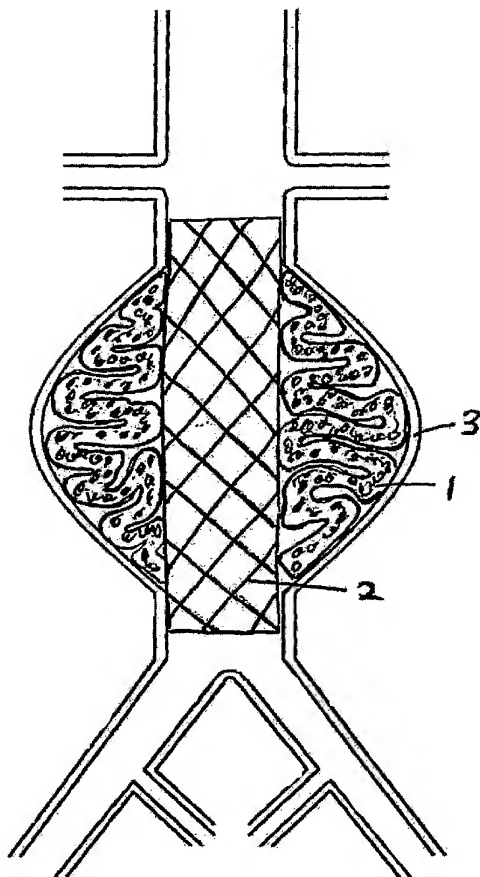
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(54) Title: DEVICES AND METHODS FOR TREATMENT OF VASCULAR ANEURYSMS



(57) Abstract: Devices and methods for the treatment of diseases in the vasculature, and more specifically, devices and methods for treatment of aneurysms (3) found in blood vessels are disclosed. In a first embodiment of the present invention, a two part prostheses, where one part is an expandable sponge structure (1) and the other part is an expandable tubular mesh structure (2), is provided. In the first embodiment, the expandable sponge structure (1) is intended to fill the aneurysm cavity (3) to prevent further dilatation of the vessel wall by creating a buffer or barrier between the pressurized pulsating blood flow and the thinning vessel wall. In the first embodiment, the expandable tubular mesh structure (2) is placed across the aneurysm (3), contacting the inner wall of healthy vessel proximal and distal to the aneurysm (3).

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## TITLE OF THE INVENTION

**DEVICES AND METHODS FOR TREATMENT  
OF VASCULAR ANEURYSMS**

## TECHNICAL FIELD AND BACKGROUND ART

**[0001]** The present invention relates to devices and methods for the treatment of diseases in the vasculature, and more specifically, devices and methods for treatment of aneurysms found in blood vessels. Aneurysms can occur in various areas of the cardiovascular system, but are commonly found in the abdominal aorta, thoracic aorta, and cerebral vessels. Aneurysms are unusual ballooning of the vessel due to loss of strength and/or elasticity of the vessel wall. With the constant pulsating pressure exerted on the vessel wall, the diseased or weakened wall can expand out and potentially rupture, which frequently leads to fatality. Prior methods of treating aneurysms have consisted of invasive surgical techniques. The technique involves a major cut down to access the vessel, and the diseased portion of the vessel is replaced by a synthetic tubular graft. Accordingly, this invasive surgical procedure has high mortality and morbidity rates.

**[0002]** Due to the inherent risks and complexities of the surgical procedures, various attempts have been made to develop minimally invasive methods to treat these aneurysms. For treatment of abdominal and thoracic aortic aneurysms, most of the attempts are catheter-based delivery of an endoluminal synthetic graft with some metallic structural member integrated into the graft, commonly called stent-grafts. One of the primary deficiencies of these systems is durability of these implants. Because catheter-based delivery creates limitations on size and structure of the implant that you can deliver to the target site, very thin synthetic grafts are attached to metallic structures, where constant interaction between the two with every heartbeat can cause wear on the graft. Also, the metallic structures often see significant cyclical loads from the pulsating blood, which can lead to fatigue failure of the metallic structure. The combination of a thin fragile graft with a metallic structure without infinite life capabilities can lead to implant failure and can ultimately lead to a fatality.

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1 [0003] While the above methods have shown some promise with regard to treating  
2 aortic aneurysms with minimally invasive techniques, there remains a need for a  
3 treatment system which doesn't rely on the less than optimal combination of a thin  
4 graft and metallic structural member to provide long-term positive results. The  
5 present invention describes various embodiments and methods to address the  
6 shortcomings of current minimally invasive devices and to meet clinical needs.

7

8

## DISCLOSURE OF INVENTION

9 [0004] In a first aspect, the present invention provides a two part prostheses where  
10 one part is an expandable sponge structure and the other part is an expandable tubular  
11 mesh structure. The expandable sponge structure is intended to fill the aneurysm  
12 cavity to prevent further dilatation of the vessel wall by creating a buffer or barrier  
13 between the pressurized pulsating blood flow and the thinning vessel wall. The  
14 expandable tubular mesh structure, which is placed across the aneurysm contacting  
15 the inner wall of healthy vessel proximal and distal to the aneurysm, serves two  
16 purposes. One, it defines the newly formed vessel lumen, even though it does not by  
17 itself provide a fluid barrier between the blood flow and the aneurysm. Two, it keeps  
18 the expandable sponge structure from protruding out of the aneurysm and into the  
19 newly formed vessel lumen. The expandable tubular mesh structure is delivered first  
20 across the aneurysm. Then, the expandable sponge structure is delivered via a  
21 catheter-based delivery system through a "cell" of the tubular mesh structure and into  
22 the aneurysm sac. When the sponge structure is deployed into the aneurysm sac and  
23 comes in contact with fluid, it will expand to a size larger than the largest opening or  
24 cell of the tubular mesh structure as to prevent the sponge structure from getting out  
25 of the aneurysm sac. The filled aneurysm sac will most likely clot off and prevent  
26 further dilation of the aneurysm and subsequent rupture. The blood flow should  
27 maintain a natural lumen where the luminal diameter is approximately defined by the  
28 diameter of the tubular mesh structure. The advantage of this system is that the  
29 sponge filler material acts like a graft but has unparalleled durability. The metallic  
30 structure can be optimized for durability as well because the size constraint is  
31 somewhat relieved due to the absence of an integrated graft material, which takes up a  
32 significant amount of space in a catheter.

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1   **[0005]** In addition, the expandable sponge structure can be used to repair existing  
2   endoluminal stent-grafts which have developed leaks. There are thousands of  
3   endoluminal stent-grafts implanted into humans to treat abdominal aortic aneurysms.  
4   That number is growing daily. The endoluminal stent-grafts are intended to exclude  
5   the aneurysm from blood flow and blood pressure by placing a minimally porous graft  
6   supported fully or partially by metallic structural members, typically called stents.  
7   The acute success rate of these devices is very high, but there are a significant number  
8   of these which develop leaks, or blood flow/pressure re-entering the aneurysm sac,  
9   some time after the procedure. If the source of the leak can be accessed by the  
10   delivery system, the expandable sponge structure can be deployed through that access  
11   point.

12   **[0006]** In another aspect, the present invention provides an inflatable tubular balloon  
13   graft. It is a tubular graft, straight or bifurcated, where its wall is not a solid structure  
14   but a hollow chamber. The chamber can be filled with a variety of materials which  
15   can dictate the mechanical properties of the prostheses. The unfilled tubular balloon  
16   graft can be folded and loaded into a catheter-based delivery system, and once in  
17   position the tubular balloon graft can be "inflated" with the filler material. The  
18   material would be filled in a fluid form and may stay a fluid form or can be solidified  
19   by various means such as UV light, heat, and time. The advantage of this system is  
20   that a metallic structure is not needed to provide structure to the graft. It is instead  
21   replaced by the injectable fluid within the chamber of the tubular balloon graft.  
22   Customization of the mechanical properties of the graft is easily accomplished by  
23   using balloon fillers of varying properties.

24   **[0007]** The tubular balloon graft can be completely non-porous, completely porous  
25   with same degree of porosity throughout the graft, completely porous with varying  
26   porosity within the graft, or partially non-porous and partially porous. Significant  
27   porosity on the very outer layer would allow for delivery of an aneurysm sac filling  
28   substance or a drug. Porosity on the ends of the graft will help promote cellular in-  
29   growth. Porosity on the ends can also be used to deliver an adhesive so that the graft  
30   can be securely attached to the vessel wall.

31   **[0008]** Another embodiment of the tubular balloon graft includes a tubular balloon  
32   graft with a bulging outer layer. This will allow the outer surface of the tubular  
33   balloon graft to fill some or all of the aneurysm. This will provide a primary or

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1 secondary barrier for the aneurysm wall from the pulsating blood flow and will  
2 provide a means to prevent migration of the graft due to the enlarged area within the  
3 graft. An alternate method of construction would be to attach a bulging outer skin to  
4 a standard tubular thin-walled graft and provide a port for injection of the filler  
5 substance. Alternatively, instead of a bulging outer skin, a very compliant outer skin  
6 can be used so that the volume of material is minimized. The compliant outer skin  
7 would be able to expand at very low inflation pressures that would be non-destructive  
8 to the aneurysm wall.

9

#### 10 BRIEF DESCRIPTION OF THE DRAWINGS

11 [0009] Figure 1A illustrates the two-part prosthesis.  
12 [0010] Figure 1B illustrates a bifurcated version of the expandable tubular mesh  
13 structure and the expandable sponge structure.  
14 [0011] Figure 1C illustrates an expandable tubular mesh structure placed across an  
15 aneurysm and the expandable sponge structure filling up the aneurysm.  
16 [0012] Figures 2A-2C illustrate the various cross-sections of the expandable sponge  
17 structure.  
18 [0013] Figure 3A illustrates a long continuous sponge structure.  
19 [0014] Figure 3B illustrates multiple short sponge structures.  
20 [0015] Figure 4 illustrates the catheter-based delivery system.  
21 [0016] Figure 5 illustrates a curved delivery catheter.  
22 [0017] Figure 6 illustrates a method of ensuring that the delivery catheter's tip stays  
23 inside the aneurysm sac.  
24 [0018] Figure 7A illustrates an expandable basket-like structure.  
25 [0019] Figure 7B illustrates an expandable braid-like structure.  
26 [0020] Figures 8 and 9 illustrate expandable tubular mesh structures.  
27 [0021] Figure 10 illustrates a delivery catheter tracked over a guidewire and placed in  
28 a stent-graft which developed a leak.  
29 [0022] Figure 11 illustrates the sponge delivered through the delivery catheter.  
30 [0023] Figures 12-15 illustrate tubular balloon grafts.  
31 [0024] Figures 16 and 17 illustrate tubular balloon grafts being expanded.  
32 [0025] Figure 18 illustrates a tubular balloon graft.

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1 [0026] Figures 19, 20A and 20 B illustrate a vascular graft with an integrated tubular  
2 balloon.

3 [0027] Figures 21A-21E illustrate a method of delivering a graft with an external  
4 balloon.

5

6

## DETAILED DESCRIPTION

7

## AND INDUSTRIAL APPLICABILITY

8 [0028] Figures 1A shows the two-part prosthesis comprising of an expandable sponge  
9 structure 1 and an expandable tubular mesh structure 2 placed in an abdominal aortic  
10 aneurysm 3 located in the infra-renal aorta not involving the iliac arteries. Figure 1B  
11 shows a bifurcated version of the expandable tubular mesh structure 2 and the  
12 expandable sponge structure 1 in an abdominal aortic aneurysm located in the infra-  
13 renal aorta and involving both iliac arteries. Figure 1C shows an expandable tubular  
14 mesh structure 2 placed across an aneurysm commonly found in cerebral arteries and  
15 the expandable sponge structure 1 filling up the aneurysm. The expandable sponge  
16 structure 1 is placed through the expandable tubular mesh structure 2 into the  
17 aneurysm, filling up the aneurysmal sac which provides a barrier between the thin  
18 fragile wall of the aneurysm and the pressurized pulsating blood. The tubular mesh  
19 structure 2 keeps the expanded sponge 1 within the confines of the aneurysm and  
20 away from the flow path.

21 [0029] The expandable sponge structure 1 is preferably made of common medical  
22 grade polymers or natural substances like collagen which can be manufactured into a  
23 sponge structure. The sponge structure can be processed in such a way so that it can  
24 be compressed to a dry condition size substantially smaller than the wet condition  
25 size, exhibiting huge expansion ratio. The expanded sponge structure can take  
26 various forms. Figures 2A-2C show the various expanded cross-sections that the  
27 expandable sponge structure 1 can be. Figure 2A shows a circular cross section,  
28 Figure 2B shows a square cross section, and Figure 2C show a triangular cross  
29 section. Any cross section can be used. The most important requirement is that it  
30 cannot escape from the aneurysm sac through a cell of the expandable tubular mesh  
31 structure 2. The length of the expandable sponge structure 1 can vary as well. Figure  
32 3A shows a long continuous structure 1. And Figure 3B shows multiple short  
33 structures 1.

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1 **[0030]** One method of delivering the sponge filler 1 into the aneurysm sac is shown  
2 by the catheter-based delivery system in Figure 4. The catheter 4 can hold the  
3 compressed sponge 1 within its lumen, and when pushed out with the plunger 5 into  
4 the blood filled aneurysm sac, the sponge will expand out to a substantially larger  
5 size. The expanded size of the sponge filler is preferably larger than the largest  
6 opening of the tubular mesh structure as to prevent the sponge from escaping the  
7 aneurysm sac. Figure 5 shows an example of a curved delivery catheter 4, where the  
8 tip is placed through a cell of the tubular mesh structure 2 and the expandable sponge  
9 structure 1 is being deployed into the aneurysm sac. It is important that the tip of the  
10 delivery catheter is through a cell of the tubular mesh structure into the aneurysm  
11 because the expandable sponge will expand very quickly after being exposed to the  
12 blood and being unconstrained by a catheter. Figure 6 shows a method of ensuring  
13 that the delivery catheter's 4 tip stays inside the aneurysm sac by having a balloon 6  
14 on the tip of it, and when inflated after the tip is within the aneurysm sac it will  
15 prevent the catheter tip from backing out of the aneurysm sac. Figure 7A shows an  
16 expandable basket-like structure 7 and Figure 7B shows an expandable braid-like  
17 structure 8 which are alternatives to having a balloon 6 on the tip of the catheter 4.

18 **[0031]** The expandable tubular mesh structure 2 can be made of a metal or of a  
19 polymer. The versions made of a metal can be self-expanding from a smaller  
20 compressed state or balloon expandable from a smaller compressed or as-cut state.  
21 The self-expanding version may be made of metals which exhibit large amounts of  
22 elasticity (i.e. nickel-titanium, spring steel, MP-35N and elgiloy) such that when they  
23 are compressed down from their expanded state to the compressed state to load into a  
24 delivery catheter, they will substantially return to their expanded condition when  
25 released from the catheter. Alternatively, shape memory metals like nickel-titanium  
26 can be used to provide large expansion ratios. The balloon expandable version may  
27 be made of metals which exhibit large permanent deformations without significantly  
28 compromising the mechanical performance. The following are some common  
29 medical grade metals which are well suited for this purpose: stainless steel, titanium,  
30 tantulum, and martensitic nickel titanium. In either the self-expanding or the balloon  
31 expandable case, the intent is to deliver the expandable tubular mesh 2 to the target  
32 site in a smaller or compressed condition via a catheter-based delivery system so that



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1 the target site can be accessed through a remote vascular access point which is  
2 conducive to a percutaneous or minimally invasive approach.  
3 **[0032]** The expandable tubular mesh structure 2 shown in Figures 1A, 1B, 1C, 5, and  
4 6 represent a generic mesh structure. Figure 8 shows an expandable tubular mesh  
5 structure where long continuous struts 9 are connected to anchoring end members 10.  
6 This allows the structure to be very low in profile in the compressed state, and the  
7 durability of this type of structure can be optimized because no radial element exists  
8 in the longitudinal struts 9. Figure 9 show an alternate expandable tubular mesh  
9 structure preferably made from a polymer such as PTFE, Polyester, Polyurethane, and  
10 the like. The structure has relatively large holes 11 to give access to the expandable  
11 sponge delivery catheter. The ends incorporate an anchoring member 12, either self-  
12 expanding or balloon expandable.

13 **[0033]** Figure 10 shows a delivery catheter 4 which has been tracked over a guidewire  
14 14, which has been placed into the aneurysm sac through an opening 15 of an existing  
15 endoluminal stent-graft 13 which developed a leak. The balloon 6 on the delivery  
16 catheter 4 was inflated after the delivery catheter 4 was positioned within the  
17 aneurysm sac. Figure 11 shows the guidewire 14 removed, and the expandable  
18 sponge structure 1 being delivered through the delivery catheter 4.

19 **[0034]** Figure 12 shows a section view of a tubular balloon graft 19 positioned across  
20 an infra-renal aortic aneurysm blocking off the flow to the aneurysm sac. The tubular  
21 balloon graft's 19 wall is made of an inner wall 16, an outer wall 17 and a chamber 18  
22 between them. The chamber 18 can be filled with various materials to dictate the  
23 mechanical properties of the prosthesis. Figure 13 shows a bifurcated tubular balloon  
24 graft 20 positioned across an infra-renal aortic aneurysm with bi-lateral iliac  
25 involvement.

26 **[0035]** The tubular balloon implant can be made of the various biocompatible  
27 materials used to make balloon catheters. Those materials include P.E.T. (Polyester),  
28 nylon, urethane, and silicone. It can also be made of other implant grade materials  
29 such as ePTFE. One method of making such a device is to start with two thin walled  
30 tubes of differing diameters. The difference between the diameters of the tubes will  
31 dictate the volume of the balloon chamber. The ends of the tubes can be sealed  
32 together with adhesive or by heat to form the balloon chamber. A communication  
33 port will be necessary to be able to fill the port with the injected material.

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1 **[0036]** The injected material can be an epoxy, a UV-curable epoxy, silicone, urethane  
2 or other type of biocompatible materials such as albumin, collagen, and gelatin glue  
3 which is injected into the balloon, and then cured in situ. Or, the injected material  
4 doesn't necessarily have to be cured. The as-delivered state may provide the  
5 appropriate mechanical properties for the application. Therefore, substances like  
6 sterile saline, biocompatible oils, or biocompatible adhesives can be left in the tubular  
7 balloon in the as-delivered state.

8 **[0037]** The tubular balloon graft can be non-porous to very porous. Figure 14 shows  
9 a version where the tubular balloon graft has a porous outer wall 24. The chamber 21  
10 of the tubular balloon graft can be used to deliver an aneurysm sac filling substance  
11 such as UV curable adhesive 22. The holes 23 which dictate the porosity of the  
12 tubular balloon graft can be created with laser drilling, etching, and other methods.  
13 The porosity can be varied in select areas of the graft. Figure 15 shows a tubular  
14 balloon graft with only the ends of the graft have porosity to either promote cellular  
15 in-growth or to inject an adhesive which allows secure attachment of the graft ends to  
16 the vessel wall.

17 **[0038]** Figure 16 shows a tubular balloon graft 19 which is being expanded from a  
18 folded condition (not shown) by a balloon catheter 25. Once expanded, the chamber  
19 18 of the tubular balloon graft 19 can be filled with the desired substance through the  
20 chamber access port 26. Figure 17 shows a tubular balloon graft 19 being expanded  
21 by an inflation process or filling the chamber 18 of the tubular balloon graft 19  
22 through the chamber access port 26.

23 **[0039]** Figure 18 shows a version of the tubular balloon graft with an outer wall 17  
24 which is substantially bulged out so that it fills some or all of the aneurysm sac.  
25 Figure 19 shows a vascular graft 27 which has an integrated balloon 28 attached to the  
26 outside surface of the graft. The balloon can be pre-bulged and folded down for  
27 delivery, or it can be a very compliant material like silicone, urethane, or latex so that  
28 it has no folds whether compressed or expanded. Figure 20A shows the same type of  
29 implant, a graft 27 with an external balloon 28, used in a cerebral vessel aneurysm 29.  
30 Figure 20B show the same implant as 20A, except that the implant balloon does not  
31 fully fill the aneurysm, which can be acceptable because the graft 27 excludes the  
32 aneurysm from the blood flow, and the primary purpose of the balloon 28 is to  
33 prevent migration of the graft 27.

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1   **[0040]** The graft 27 can be made of commonly used implant polymers such as PTFE,  
2   Polyester, Polyurethane, etc. The balloon 28 surrounding the graft can be made of the  
3   same commonly used vascular implant materials as well. The graft and balloon  
4   materials can be different, but it is commonly known that using the same material for  
5   both would facilitate processing/manufacturing. The theory is that the balloon 28  
6   would preferentially only deploy into the aneurysm sac where the resistance to  
7   expansion is minimal as compared to the vessel wall. The graft 27 would provide the  
8   primary barrier between the pressurized blood and the thin wall of the aneurysm.  
9   Secondarily, the balloon itself provides a buffer from the pressurized blood. The  
10   balloon's 28 primary function, however, is to hold the graft 27 in place. Since the  
11   expanded section of the implant is "locked" into the aneurysm, the graft 27 should not  
12   migrate. Also, the balloon 28, in the filled state, will provide hoop strength to the  
13   graft 27.

14   **[0041]** Figures 21A-21E demonstrate one method of delivering a graft with an  
15   external balloon to the target site. Figure 21A shows the implant loaded onto a  
16   balloon delivery catheter 30 with an outer sheath 32 and positioned over a guide wire  
17   31 at the aneurysm target site. Figure 21B shows that once in position, the outer  
18   sheath 32 is withdrawn. Figure 21C shows the balloon delivery catheter 33 being  
19   inflated, pushing the implant 34 against the healthy vessel walls on both sides of the  
20   aneurysm. Figure 21D shows that the balloon delivery catheter 30 may also have an  
21   implant balloon inflation port 35 which can now be used to fill up the implant balloon  
22   28 with a biocompatible substance. The substance can be sterile saline, contrast  
23   agent, hydrogel, and UV cure adhesive to name a few. Most likely, low inflation  
24   pressures would be used to fill the implant balloon 28. Figure 21E shows that once  
25   the implant balloon 28 is filled, the implant balloon inflation port 35 can be detached  
26   and the delivery catheter 30 removed.

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## CLAIMS

1  
2 We claim:

- 3 1. An assembly for filling an aneurysm sac comprising:  
4 an expandable mesh comprising cells, and  
5 an expandable space-occupying device having a cross-section, wherein the  
6 device is placed in the aneurysm sac and the mesh prevents the device from escaping  
7 from the aneurysm sac.  
8 2. The assembly of Claim 1, wherein the device has an expanded size larger than the  
9 largest cell.  
10 3. The assembly of Claim 1, wherein the mesh comprises an anchoring member.  
11 4. The assembly of Claim 1, wherein the device comprises polymer.  
12 5. The assembly of Claim 1, wherein the device comprises collagen.  
13 6. The assembly of Claim 1, wherein the cross-section of the device is circular.  
14 7. The assembly of Claim 1, wherein the cross-section of the device is square.  
15 8. The assembly of Claim 1, wherein the cross-section of the device is triangular.  
16 9. The assembly of Claim 1, wherein the mesh comprises long continuous struts.  
17 10. The assembly of Claim 1, wherein the device comprises a sponge.  
18 11. The assembly of Claim 10, wherein the device has an expanded size larger than  
19 the largest cell.  
20 12. The assembly of Claim 10, wherein the mesh comprises an anchoring member.  
21 13. The assembly of Claim 10, wherein the device comprises polymer.  
22 14. The assembly of Claim 10, wherein the device comprises collagen.  
23 15. The assembly of Claim 10, wherein the cross-section of the device is circular.  
24 16. The assembly of Claim 10, wherein the cross-section of the device is square.  
25 17. The assembly of Claim 10, wherein the cross-section of the device is triangular.  
26 18. The assembly of Claim 10, wherein the mesh comprises long continuous struts.  
27 19. A device for filling an aneurysm cavity comprising:  
28 A graft comprising an inner wall and an outer wall, wherein the inner wall and  
29 the outer wall form a chamber, and wherein the chamber is filled with a filler  
30 material, and wherein the graft is detached from a delivery catheter.  
31 20. The device of Claim 19, wherein the filler material comprises an epoxy.  
32 21. The device of Claim 19, wherein the filler material comprises silicone.  
33 22. The device of Claim 19, wherein the filler material comprises urethane.

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- 1 23. The device of Claim 19, wherein the filler material comprises albumin.
- 2 24. The device of Claim 19, wherein the filler material comprises collagen.
- 3 25. The device of Claim 19, wherein the filler material comprises gelatin glue.
- 4 26. The device of Claim 19, wherein the filler material comprises saline.
- 5 27. The device of Claim 19, wherein the filler material comprises a contrast agent.
- 6 28. The device of Claim 19, wherein the filler material comprises a biocompatible
- 7 oil.
- 8 29. The device of Claim 19, wherein the filler material comprises a biocompatible
- 9 adhesive.
- 10 30. The device of Claim 19, wherein the filler material is cured by UV light.
- 11 31. The device of Claim 19, wherein the outer wall is porous.
- 12 32. The device of Claim 19, wherein the graft is non-porous.
- 13 33. A method for filling an aneurysm sac comprising,
- 14 placing an expandable structure across an aneurysm,
- 15 filling the aneurysm sac with a space-occupying device.
- 16 34. The method of Claim 33, wherein filling comprises placing a delivery catheter
- 17 into the aneurysm sac.
- 18 35. The method of Claim 34, wherein filling further comprises inflating a balloon on
- 19 the delivery catheter after the delivery catheter is placed into the aneurysm cavity.
- 20 36. The method of Claim 35, wherein filling further comprises delivering the device
- 21 through the delivery catheter.
- 22 37. The method of Claim 36, wherein delivering the device comprises pushing the
- 23 device out of the catheter with a plunger.
- 24 38. The method of Claim 33, wherein the space-occupying device comprises a
- 25 sponge.
- 26 39. The method of Claim 38, wherein filling comprises placing a delivery catheter
- 27 into the aneurysm sac.
- 28 40. The method of Claim 39, wherein filling further comprises inflating a balloon on
- 29 the delivery catheter after the delivery catheter is placed into the aneurysm cavity.
- 30 41. The method of Claim 40, wherein filling further comprises delivering the device
- 31 through the delivery catheter.
- 32 42. The method of Claim 41, wherein delivering the device comprises pushing the
- 33 device out of the catheter with a plunger.

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- 1 43. A method for filling an aneurysm cavity with a graft comprising an implant  
2 balloon, the method comprising,  
3 positioning the graft at the aneurysm, wherein the graft is loaded on a delivery  
4 catheter,  
5 inflating the implant balloon, and  
6 detaching and removing the catheter from the graft.
- 7 44. The method of Claim 43, wherein inflating the balloon comprises inflating with  
8 an epoxy.
- 9 45. The method of Claim 43, wherein inflating the balloon comprises inflating with  
10 silicone.
- 11 46. The method of Claim 43, wherein inflating the balloon comprises inflating with  
12 urethane.
- 13 47. The method of Claim 43, wherein inflating the balloon comprises inflating with  
14 albumin.
- 15 48. The method of Claim 43, wherein inflating the balloon comprises inflating with  
16 collagen.
- 17 49. The method of Claim 43, wherein inflating the balloon comprises inflating with  
18 gelatin glue.
- 19 50. The method of Claim 43, wherein inflating the balloon comprises inflating with  
20 saline.
- 21 51. The method of Claim 43, wherein inflating the balloon comprises inflating with a  
22 contrast agent.
- 23 52. The method of Claim 43, wherein inflating the balloon comprises inflating with a  
24 biocompatible oil.
- 25 53. The method of Claim 43, wherein inflating the balloon comprises inflating with a  
26 biocompatible adhesive.
- 27 54. The method of Claim 43, wherein inflating the balloon comprises inflating with a  
28 UV cure adhesive.  
29

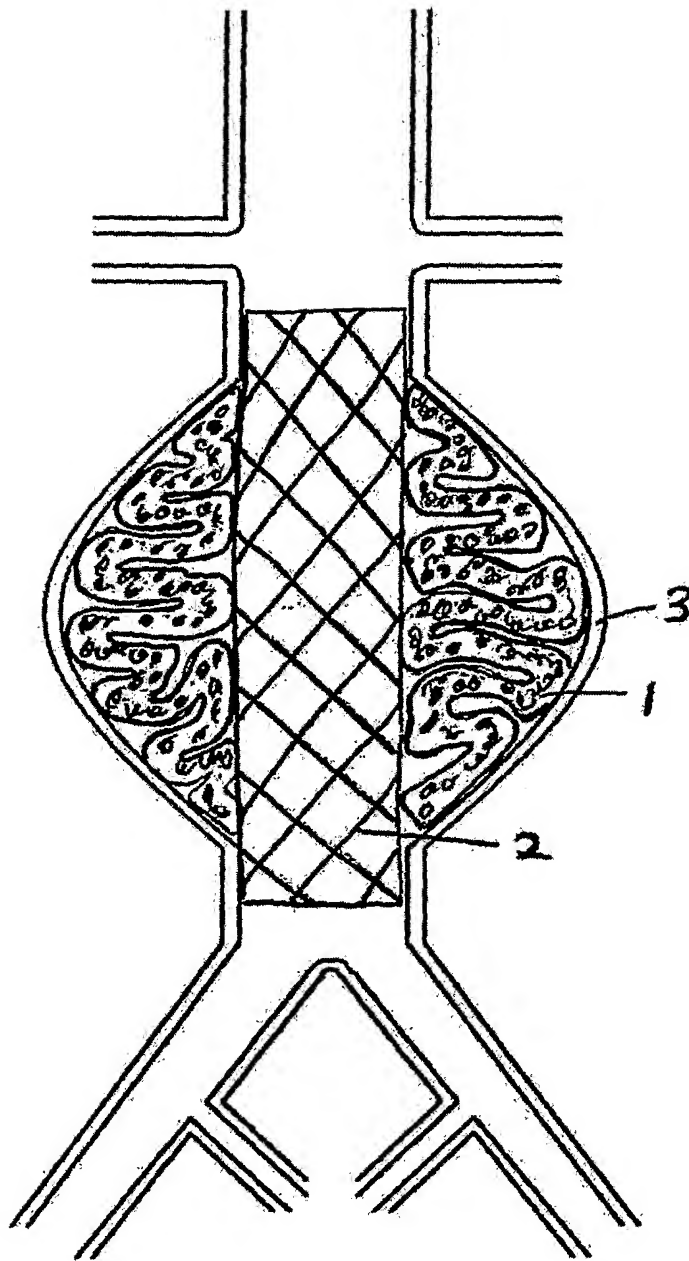


FIGURE 1A

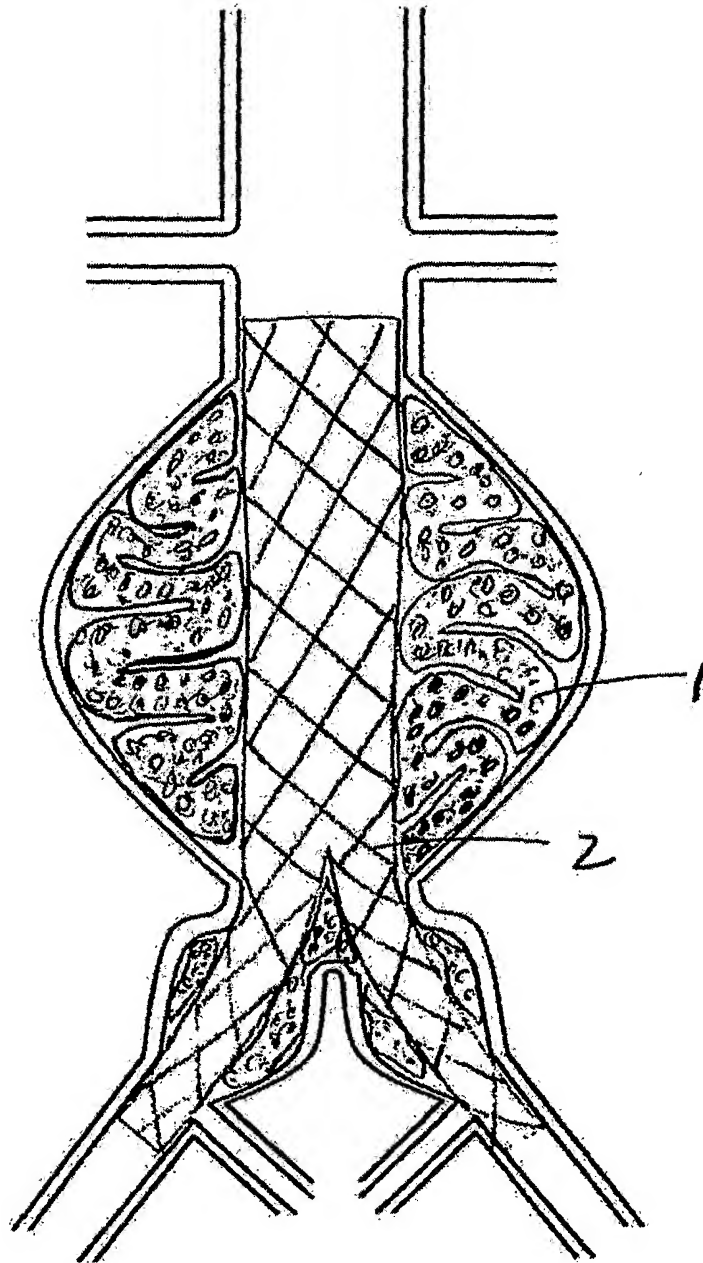


FIGURE 1B



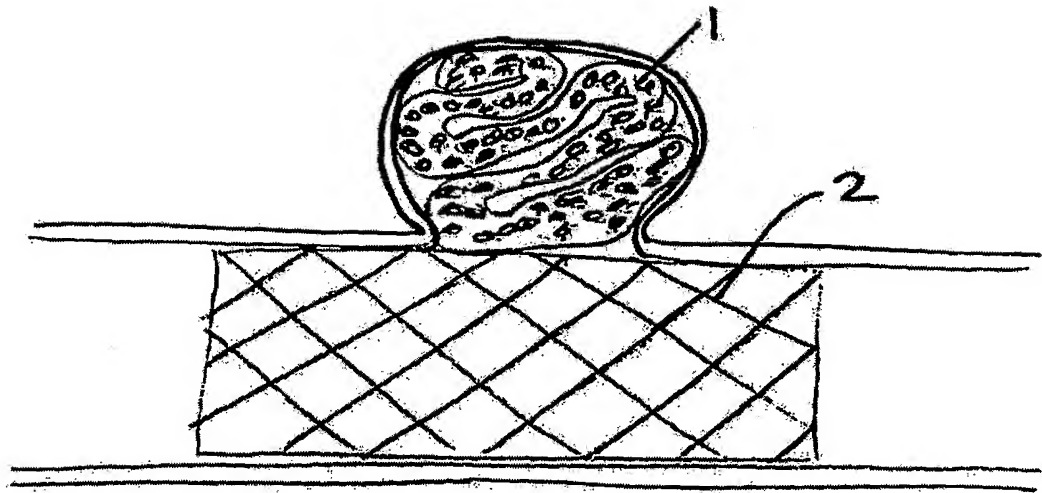


FIGURE 1C

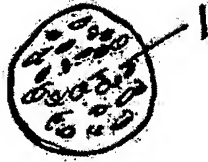


FIGURE 2A

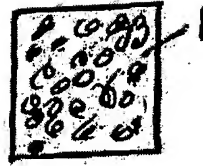


FIGURE 2B



FIGURE 2C

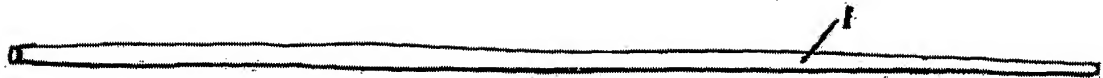


FIGURE 3A

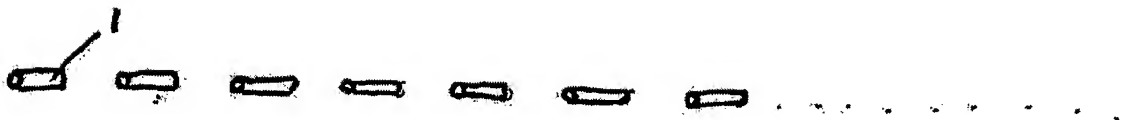


FIGURE 3B

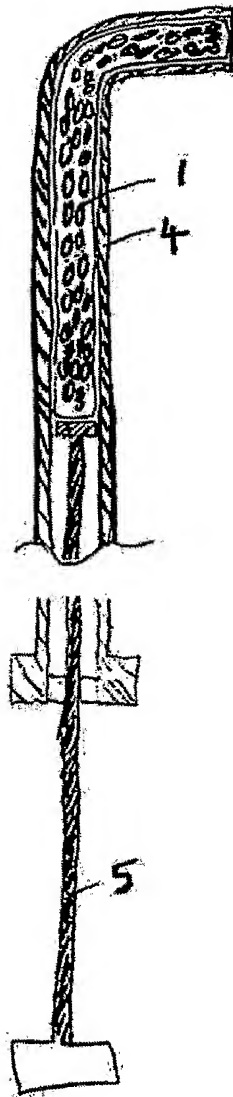


FIGURE 4

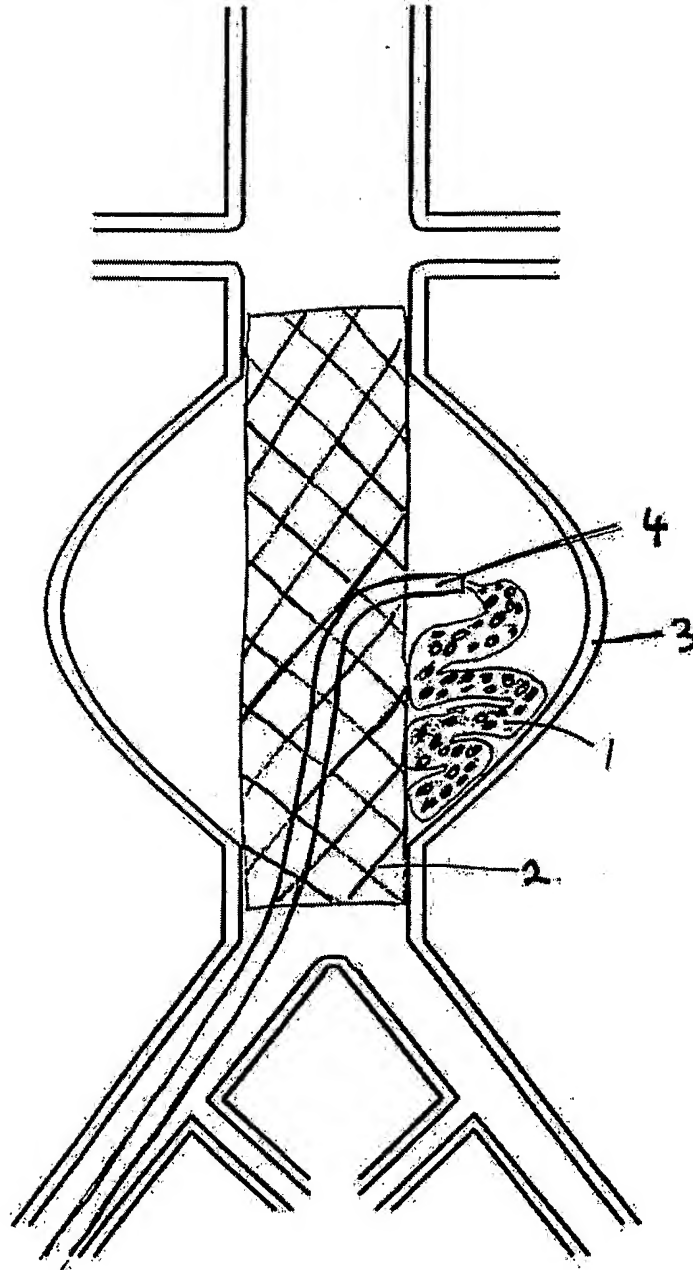


Figure 5

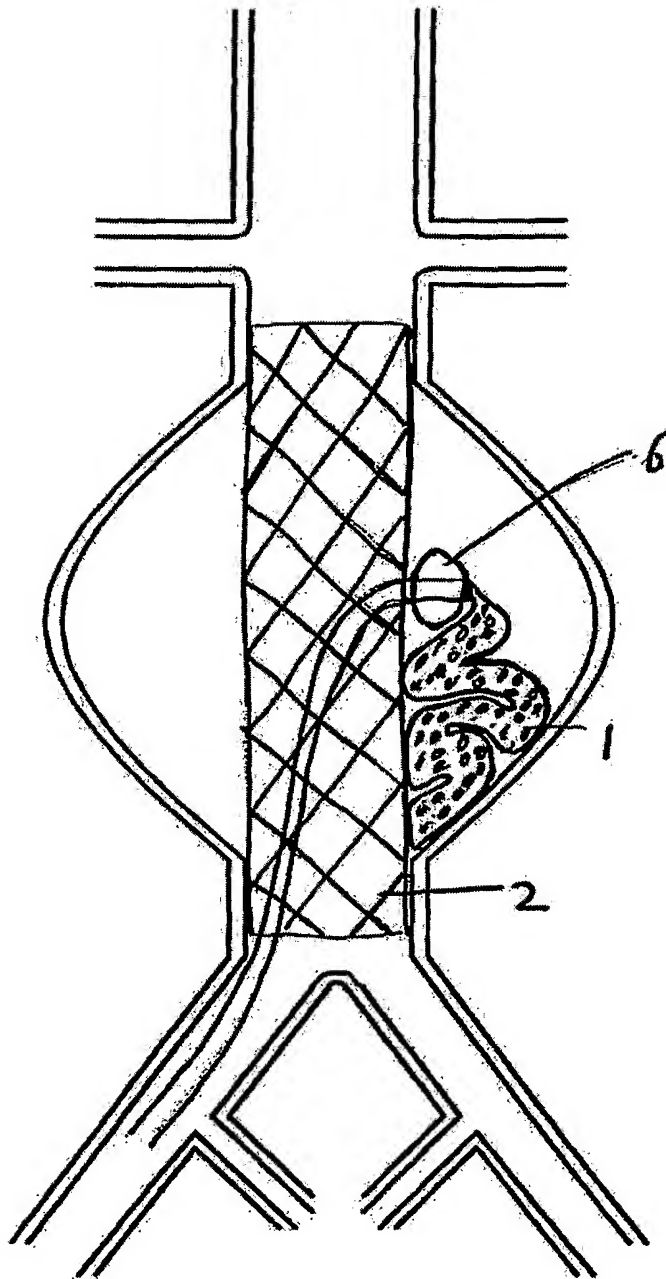


FIGURE 6

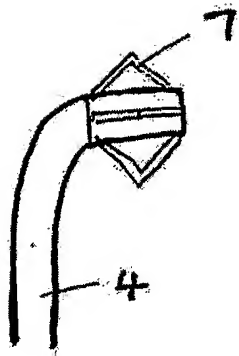


FIGURE 7A

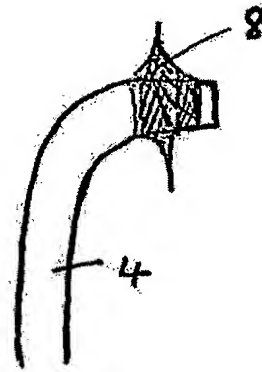


FIGURE 7B

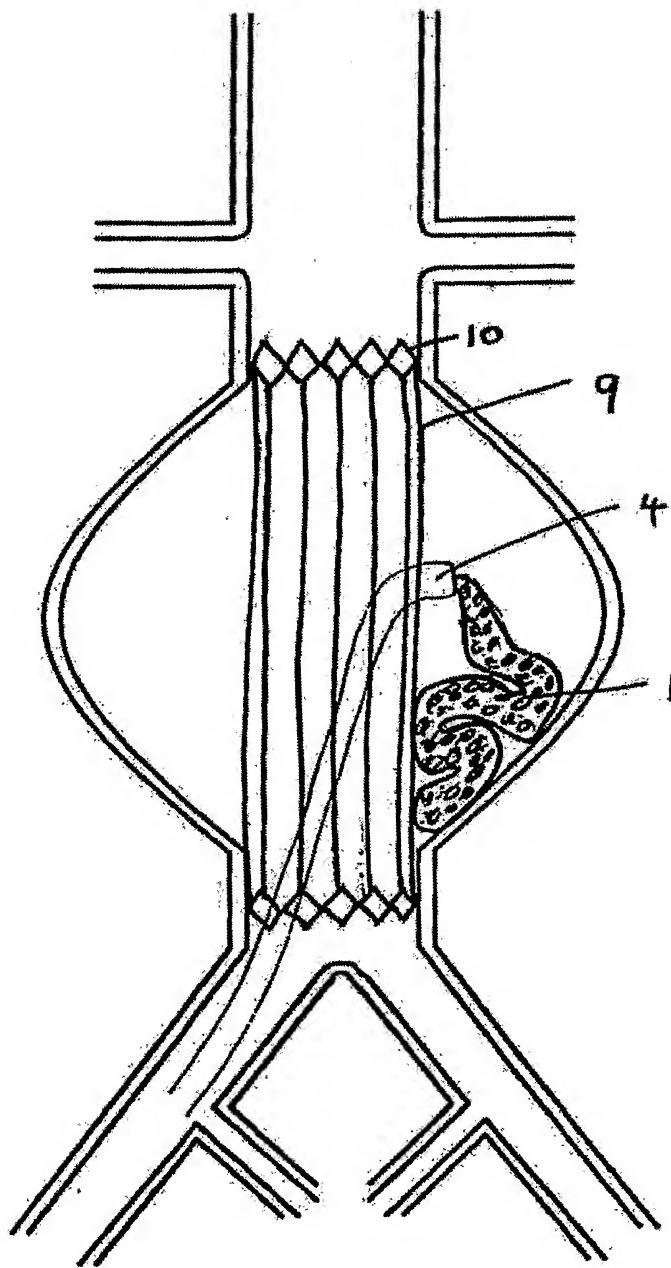


FIGURE 8

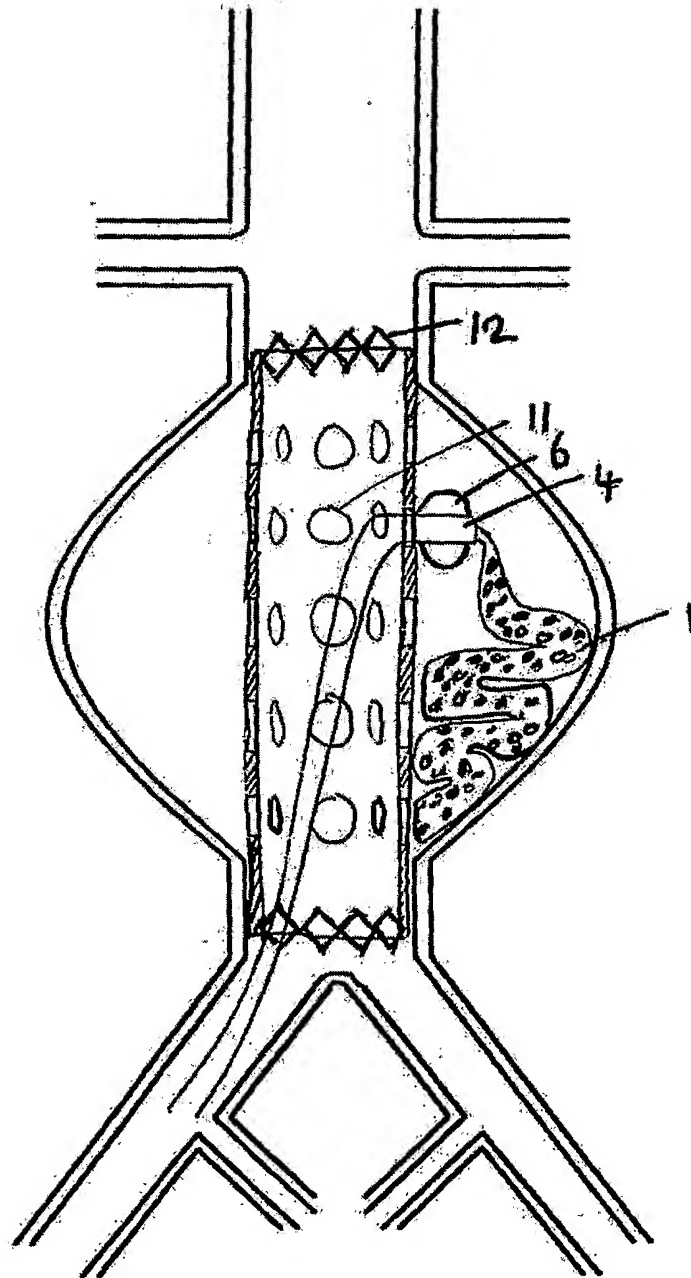


FIGURE 9



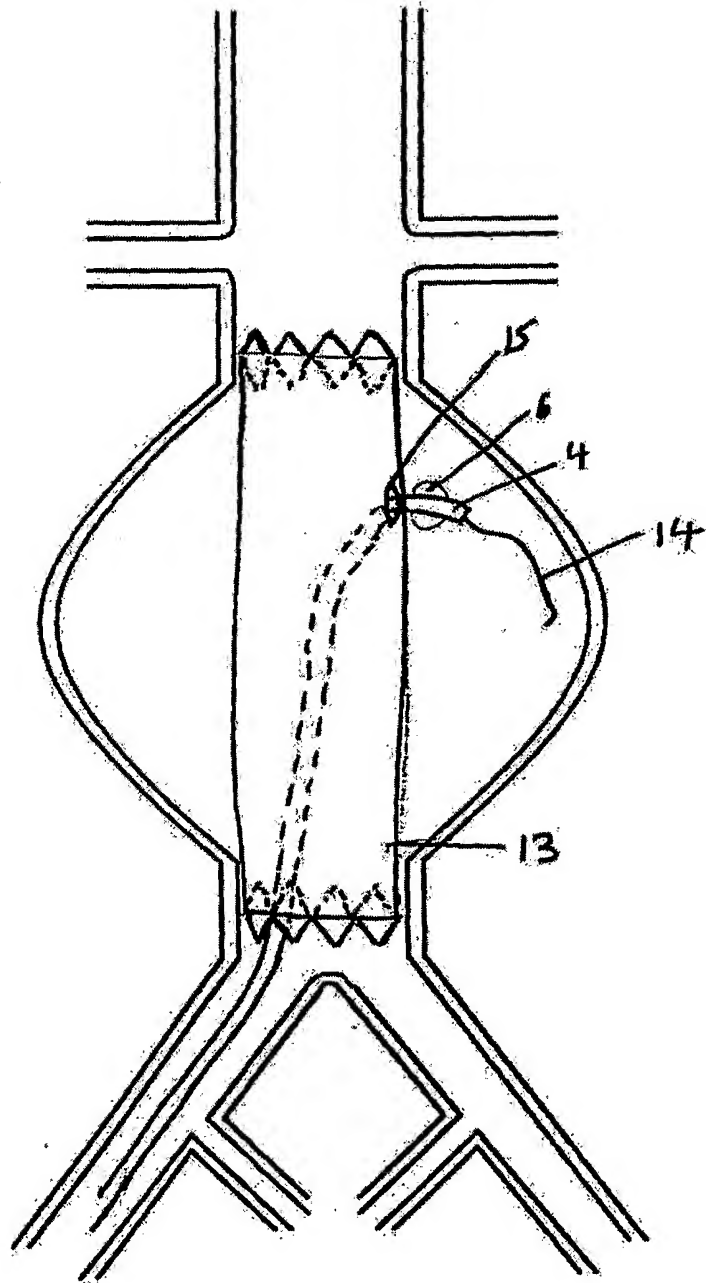


FIGURE 10

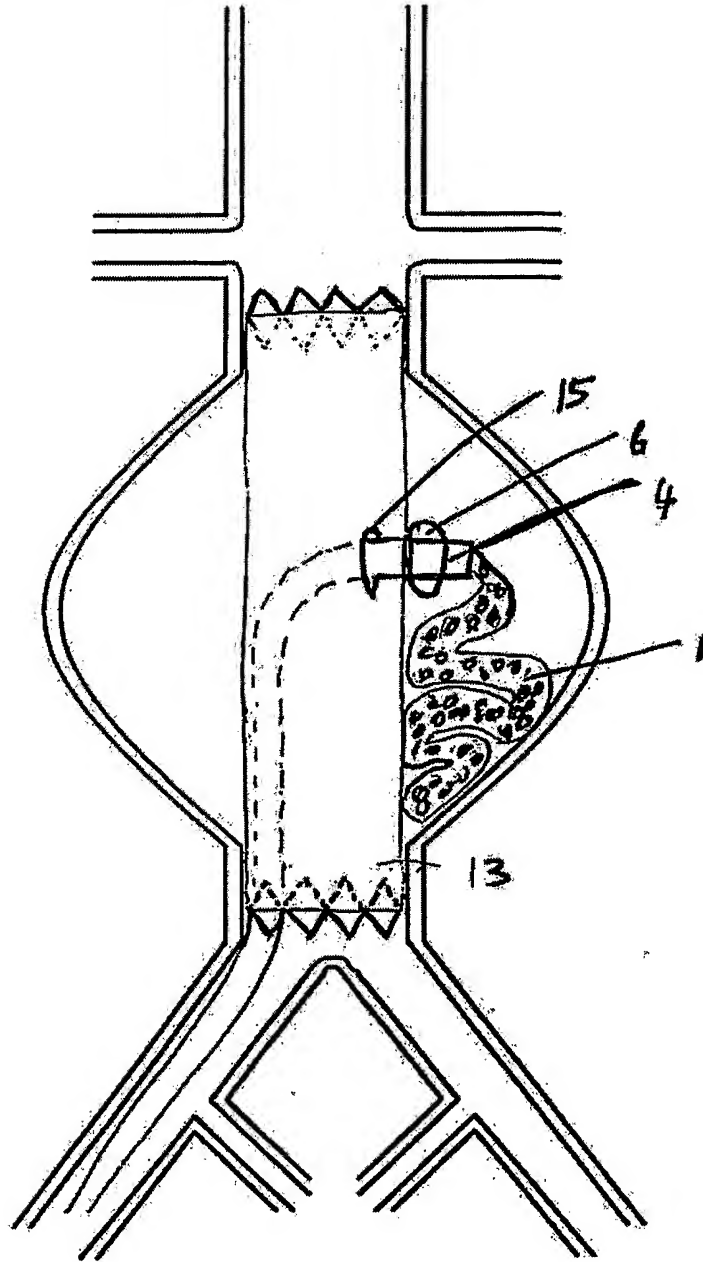


FIGURE 11

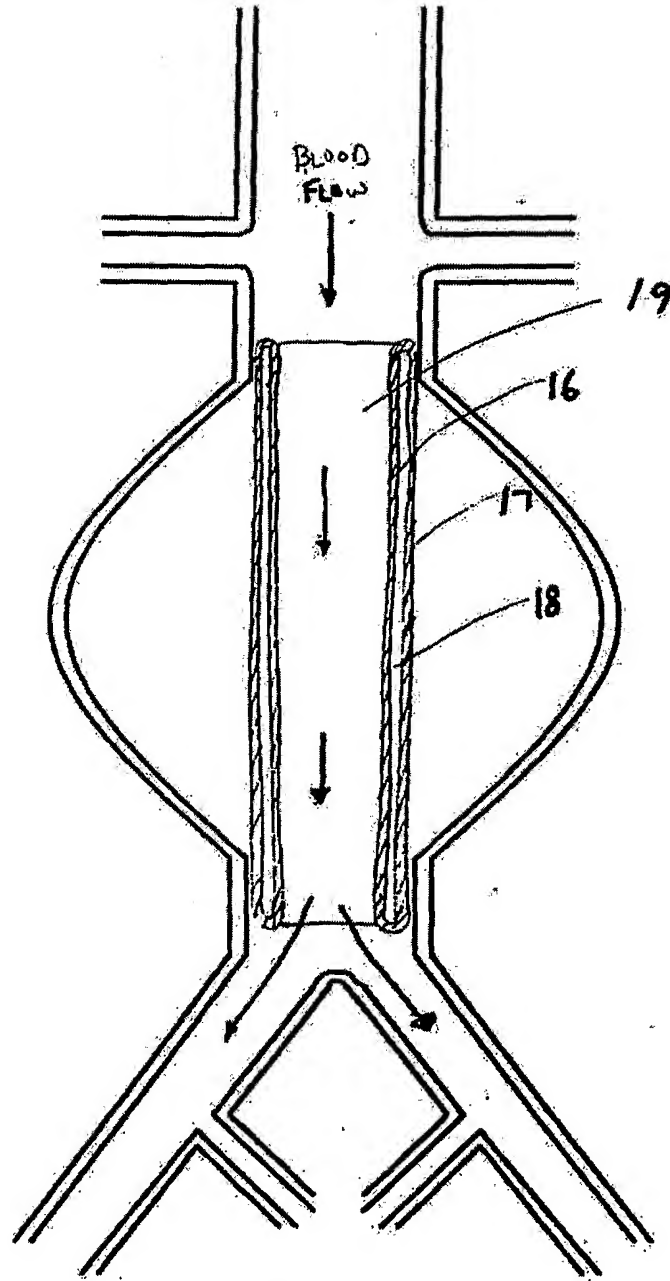


FIGURE 12

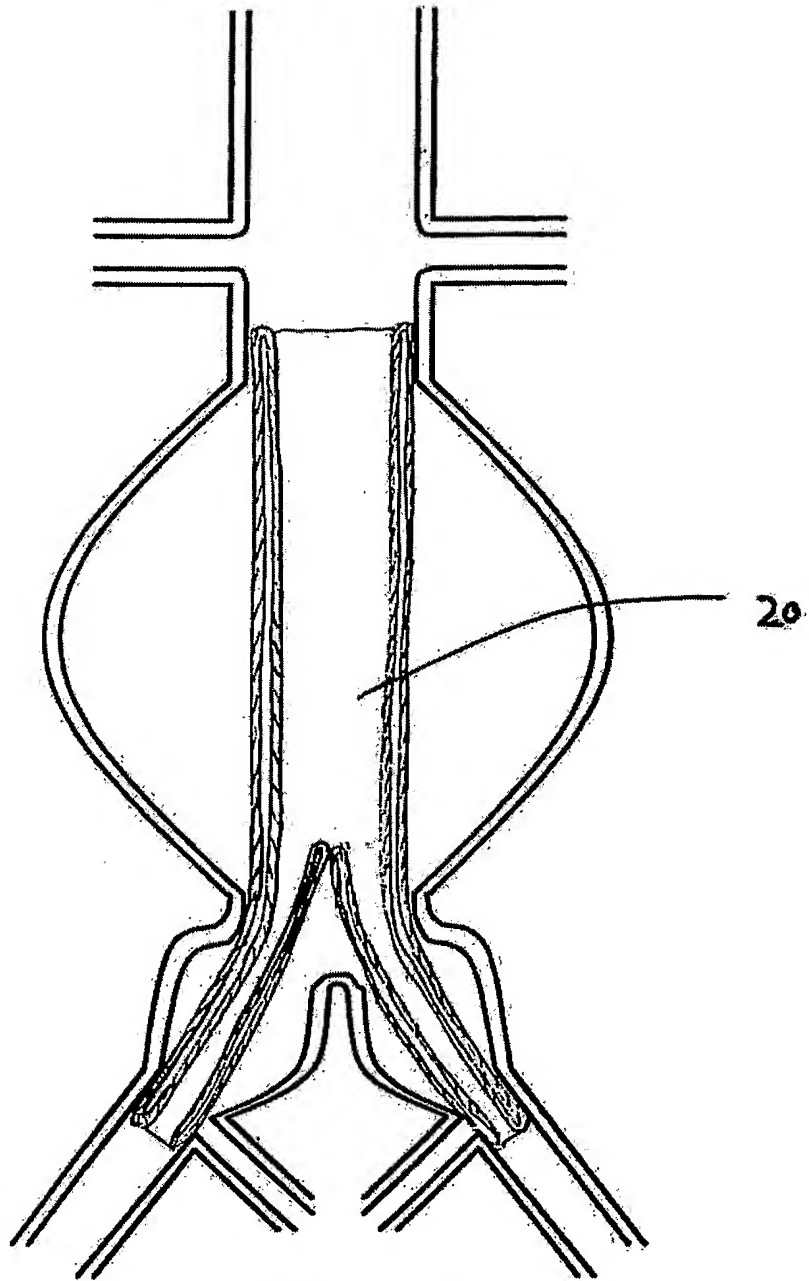


FIGURE 13

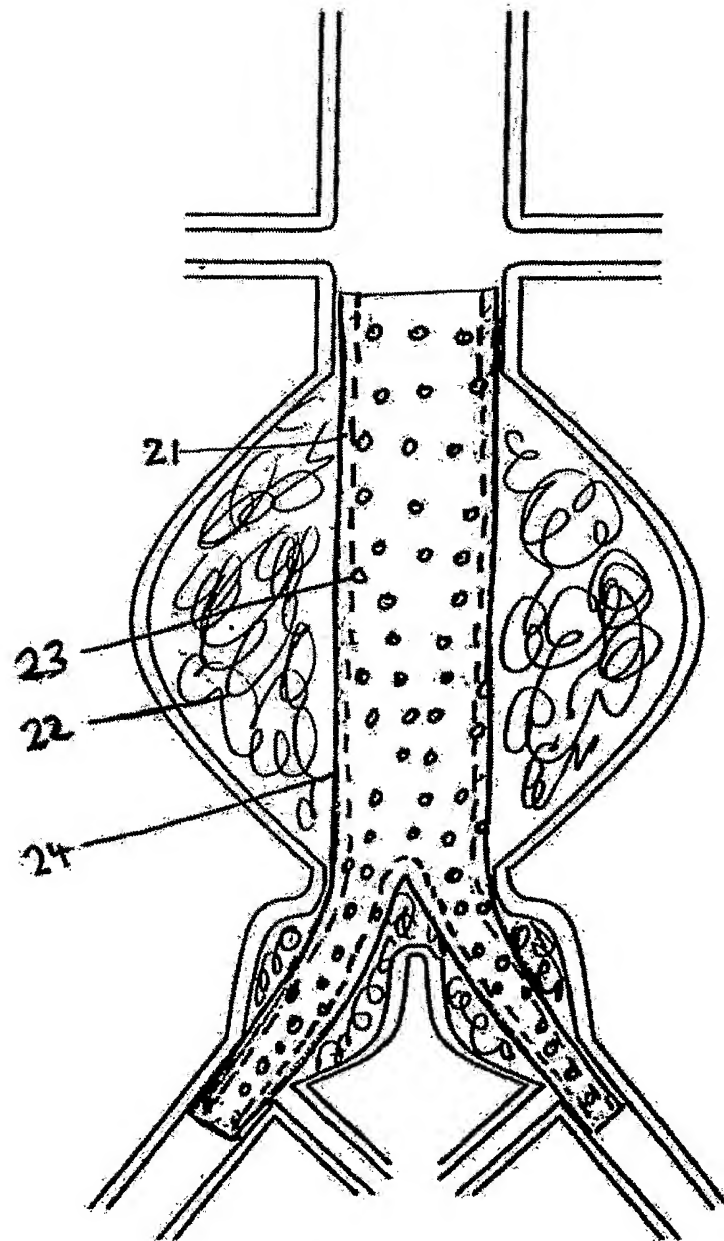


FIGURE 14

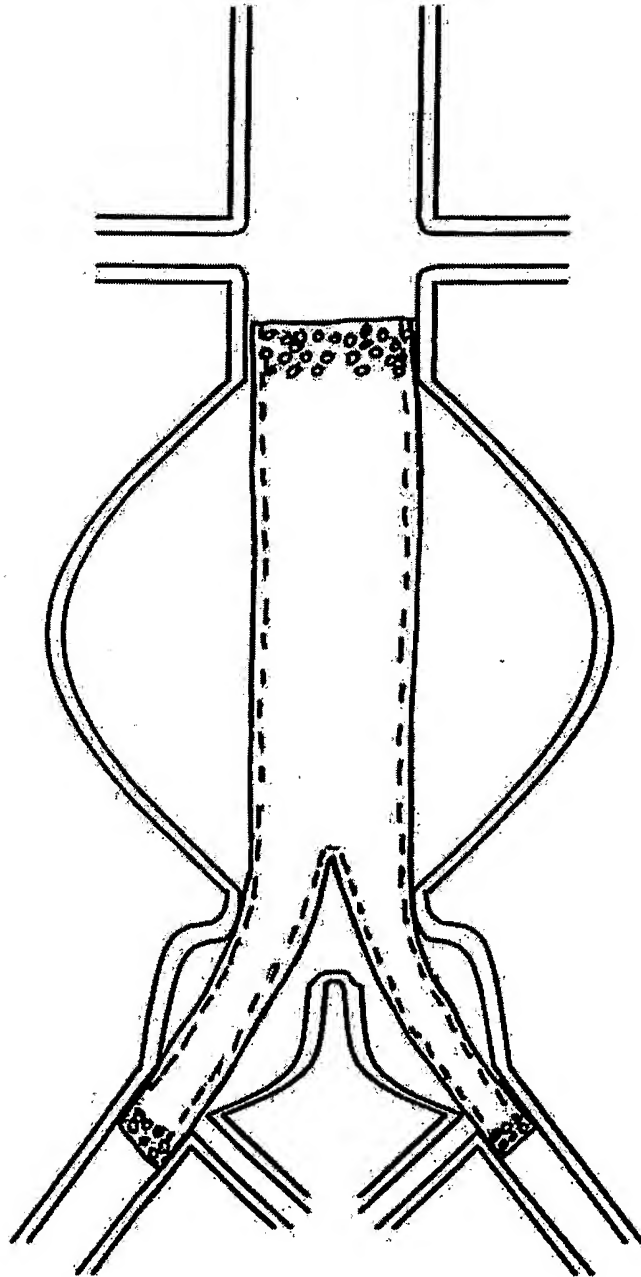


FIGURE 15

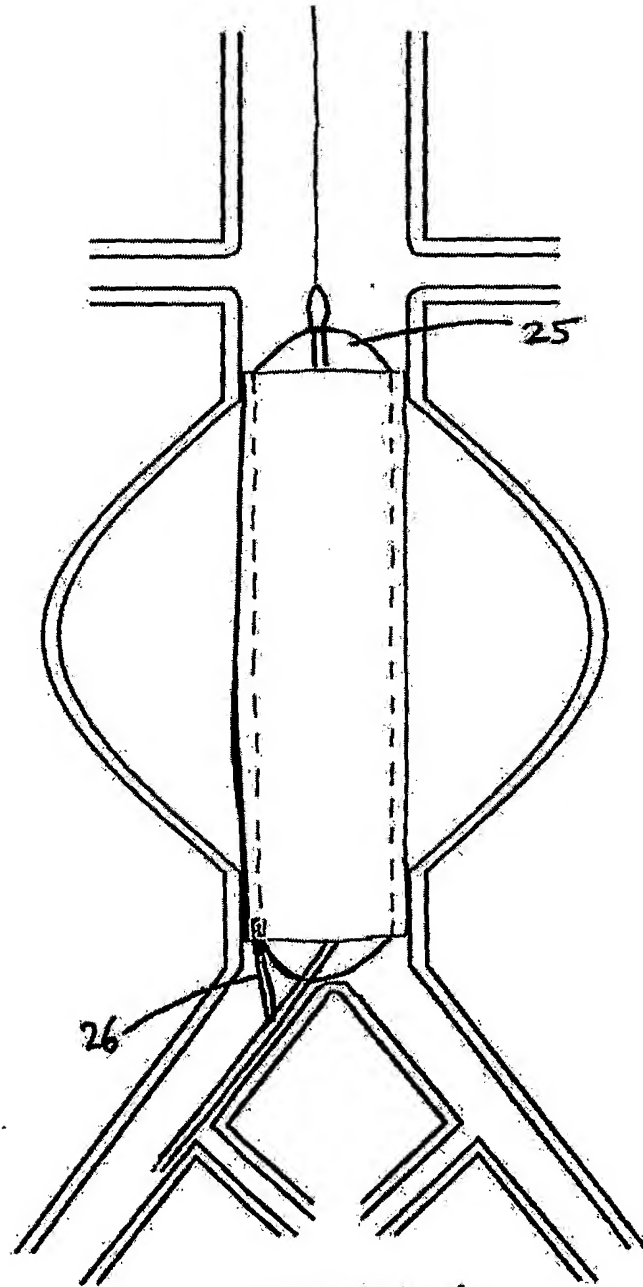


FIGURE 16

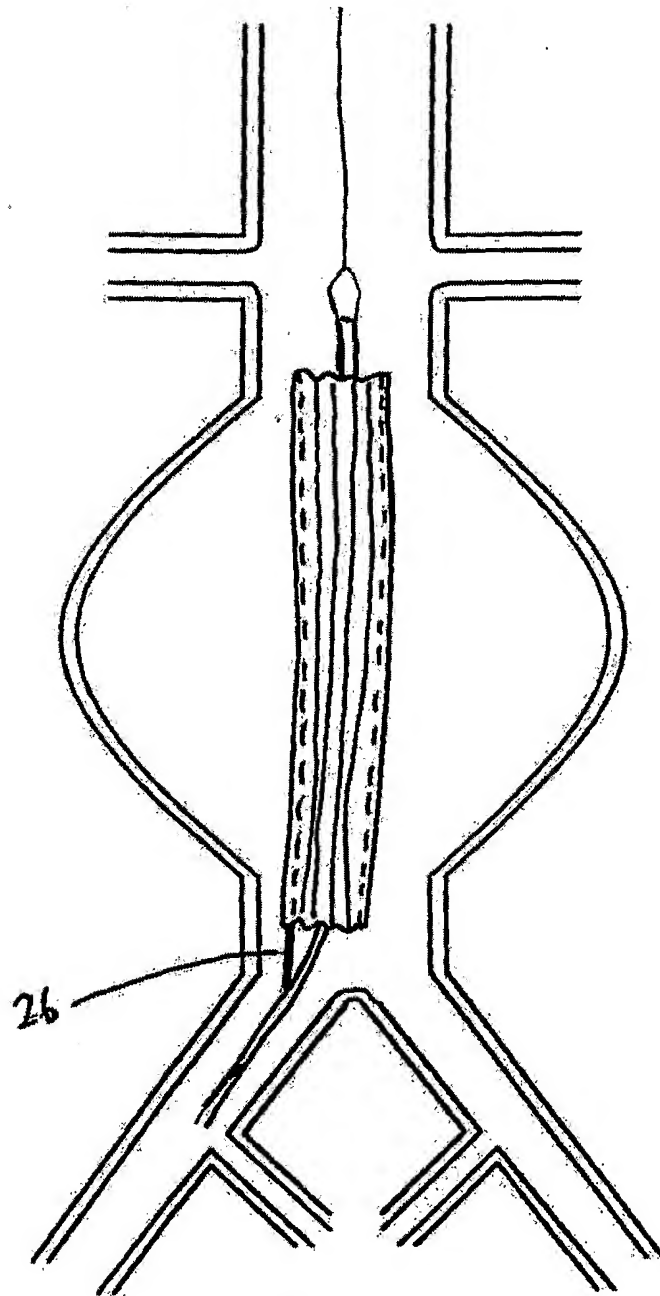


FIGURE 17



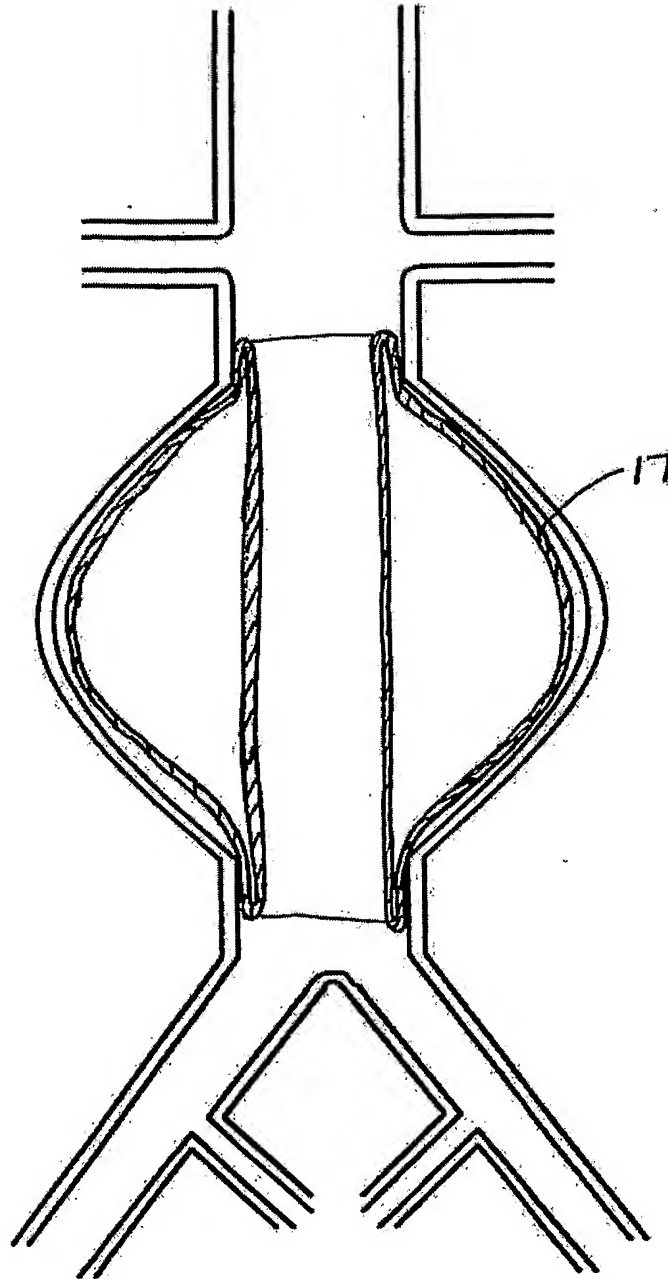


FIGURE 18

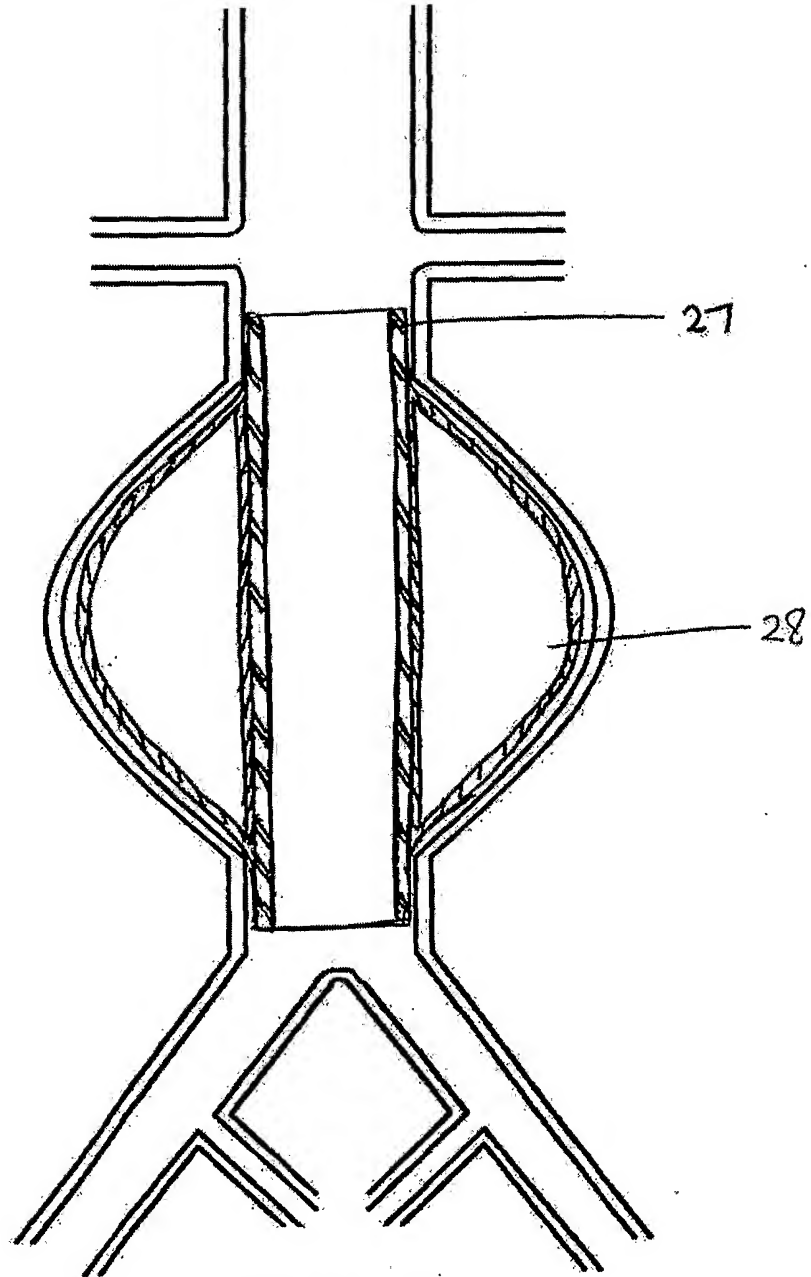


FIGURE 19

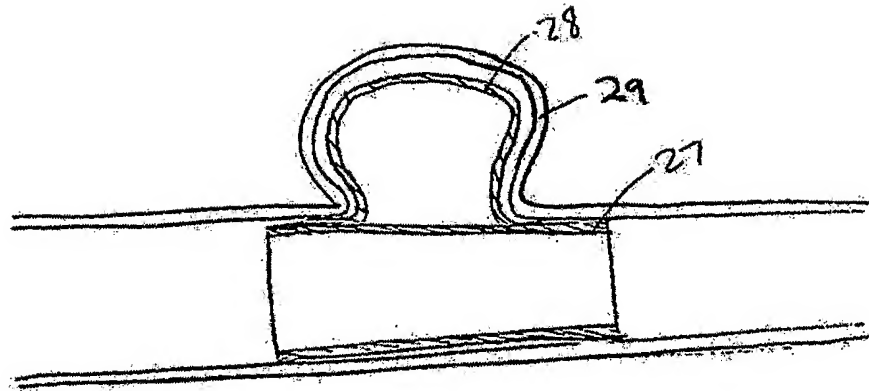


FIGURE 20 A

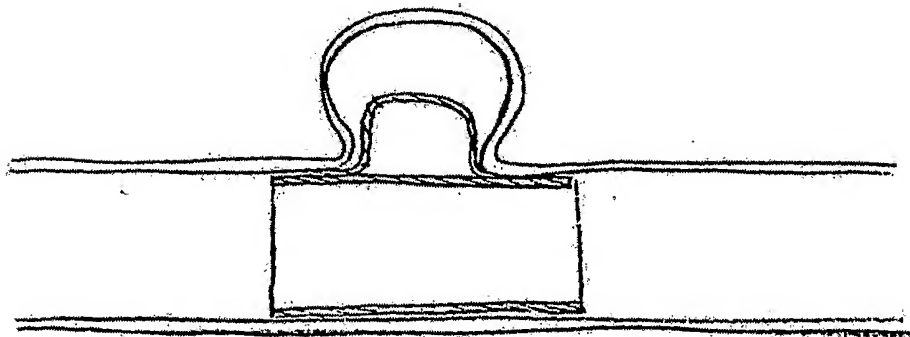


FIGURE 20 B

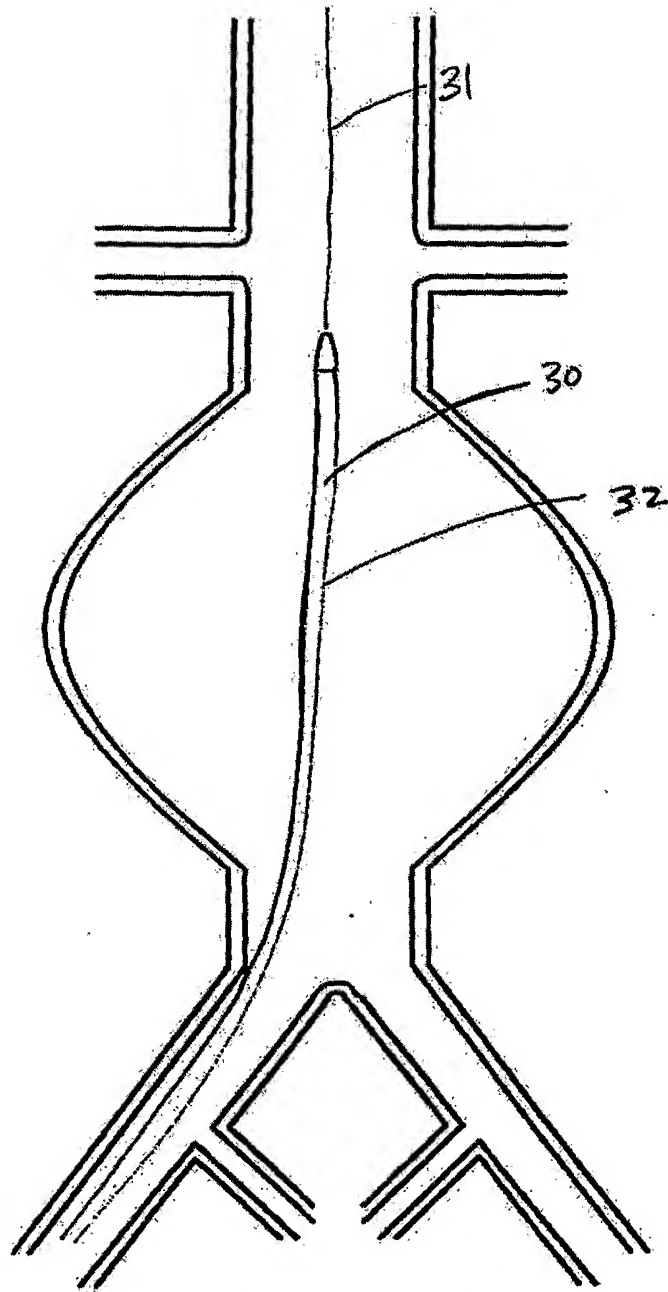


FIGURE 21A

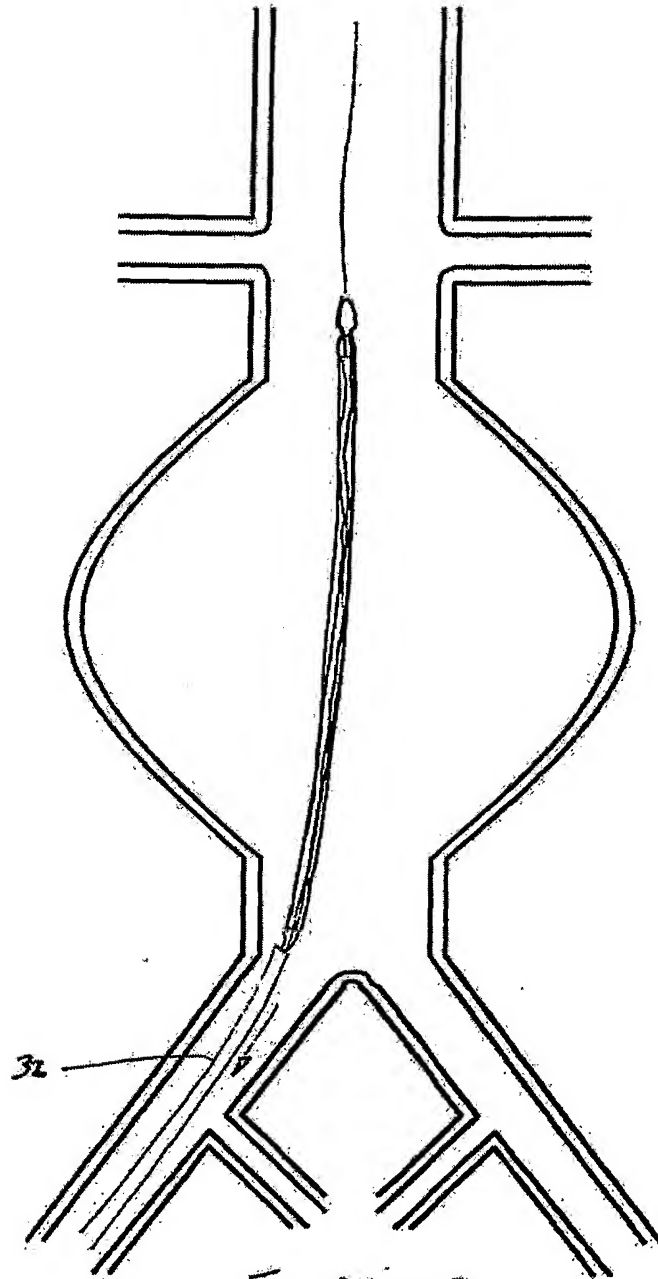


FIGURE 21B

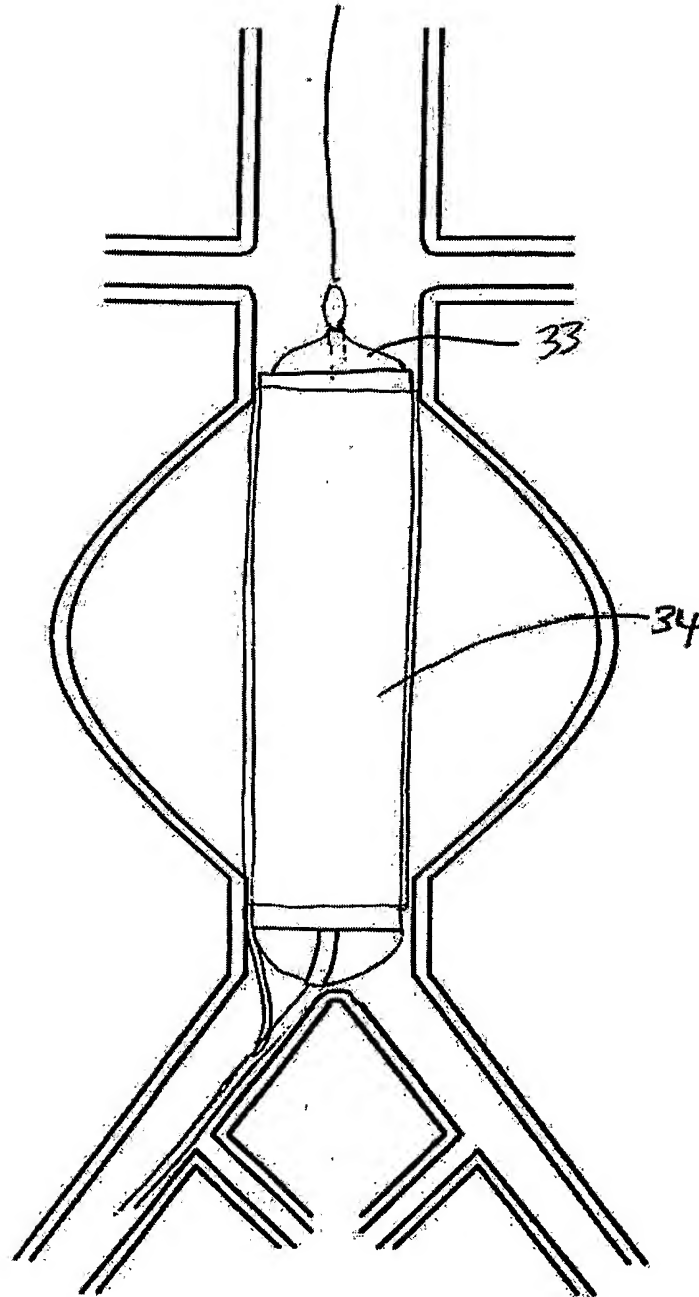


FIGURE 21 C

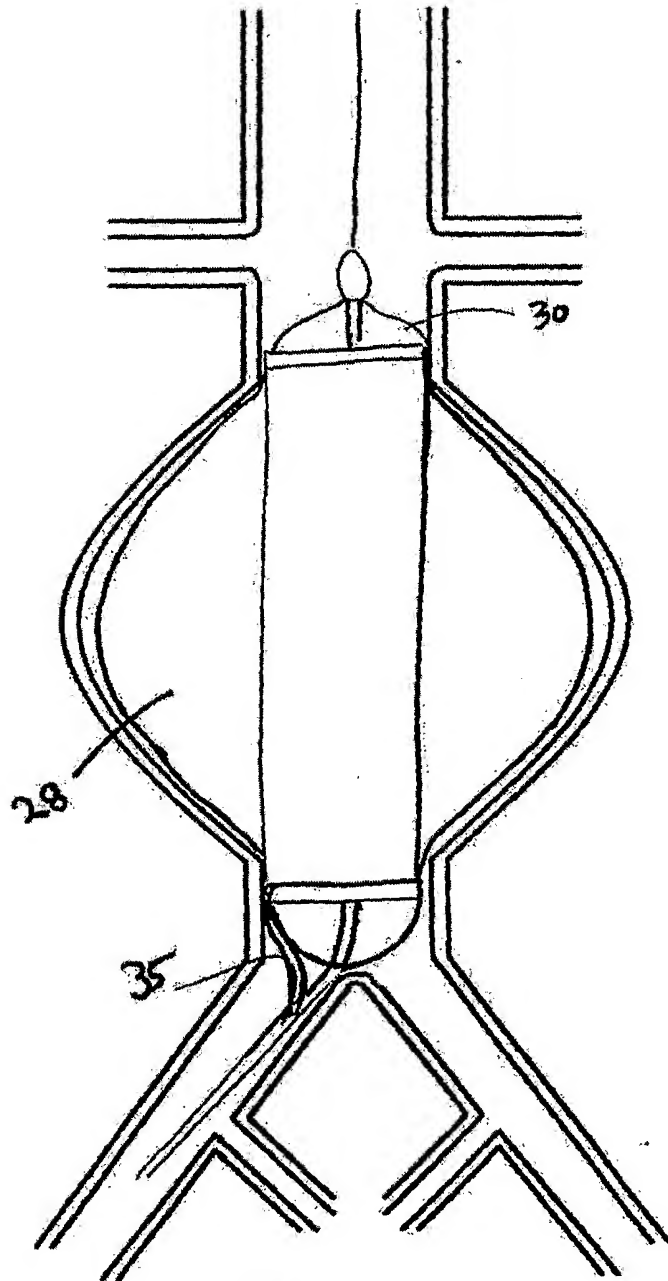


FIGURE 21D

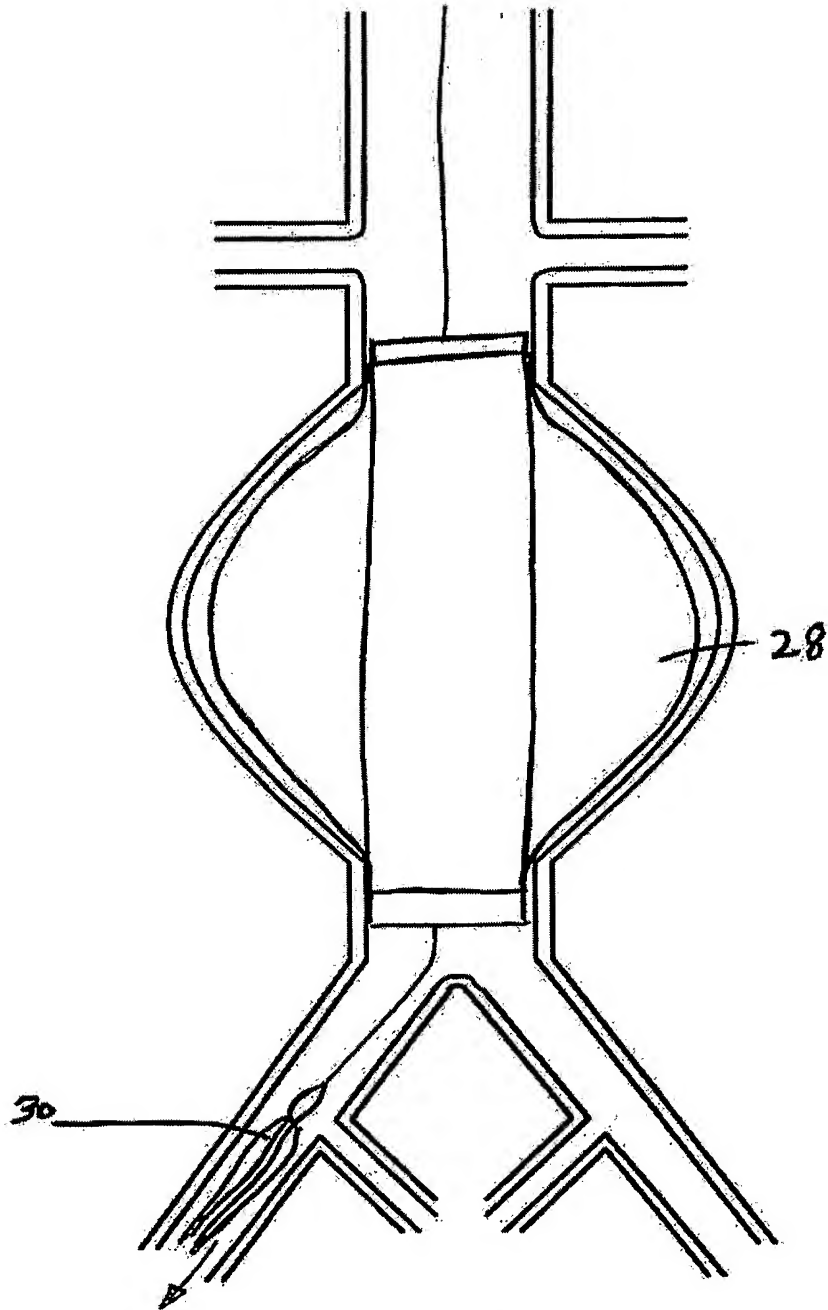


FIGURE 21E



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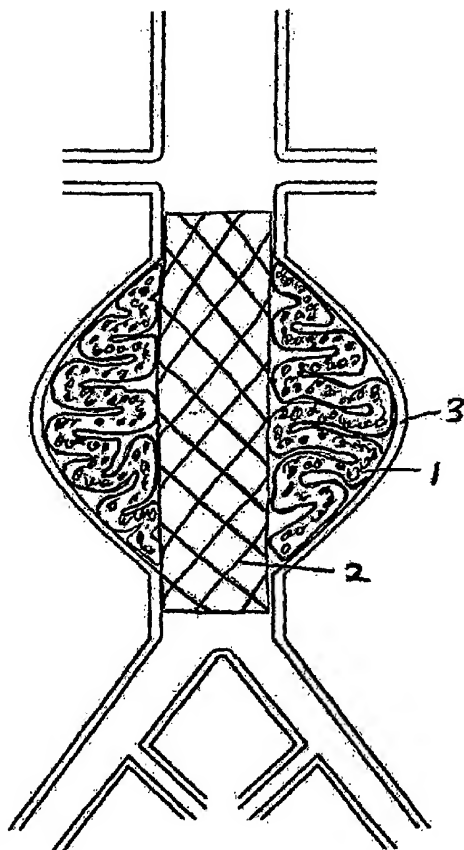
(74) Agent: **LEVINE, David, A.**; P.O. Box 61180, Palo Alto, CA 94306-1180 (US).

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[Continued on next page]

(54) Title: DEVICES AND METHODS FOR TREATMENT OF VASCULAR ANEURYSMS



(57) Abstract: Devices and methods for the treatment of diseases in the vasculature, and more specifically, devices and methods for treatment of aneurysms (3) found in blood vessels are disclosed. In a first embodiment of the present invention, a two part prostheses, where one part is an expandable sponge structure (1) and the other part is an expandable tubular mesh structure (2), is provided. In the first embodiment, the expandable sponge structure (1) is intended to fill the aneurysm cavity (3) to prevent further dilatation of the vessel wall by creating a buffer or barrier between the pressurized pulsating blood flow and the thinning vessel wall. In the first embodiment, the expandable tubular mesh structure (2) is placed across the aneurysm (3), contacting the inner wall of healthy vessel proximal and distal to the aneurysm (3).



ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/37500

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US CL : 606/200

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Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,344,041 B1 (KUPIECKI ET AL.) 05 FEBRUARY 2002, COLUMN 6, LINE 32 TO COLUMN 9, LINE 42.	1-18, 33-42
X	US 6,293,960 B1 (KEN) 25 SEPTEMBER 2001, COLUMN 4, LINE 1 TO COLUMN 5, LINE 23.	19-32, 43-54

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